



FLIR SYSTEMS BOSTON

2156 10 SEP 19 10:33

Docket Management Branch (HFA-305)
Food and Drug Administration, Rm 1-23
12420 Parklawn Drive
Rockville, MD 20857

September 3, 1999

Dear Sir:

Re: Variance Application for FDA Access Number 9811735

The laser product submitted under the subject FDA Access Number is certified to meet ANSI Z136.1. However, the ANSI standard for radiant energy is more than the radiant energy required by 21CFR 1040.10(d) and 1040.10(e). This is an application for variance from such standard per 21 CFR 1010.5(a)(1). The US agency in this case is the Crane Division, US Navy.

Attached herein is information to support a request for variance.

Should you need further information, please contact the undersigned:

FLIR Boston, Inc.
16 Esquire Road
North Billerica, MA 01862-2598
Telephone: 978-901-8379
e-mail kwong@inframetrics.com

Kin Wong

Kin Wong
Quality Assurance Manager

Attachment – Two extra copies
CC: V. Pollock, Crane Division, US Navy
T. Stine, Crane Division, US Navy

The Forward Looking Infrared Company

FLIR Systems Boston • 16 Esquire Road • North Billerica, MA 01862 • USA
Telephone: +1(978) 901 8000 • Fax: +1(978) 901 8887
www.flir.com

99V-4065

VAR 1

Application for Variance – Access Number 9811735
Information Required per 21 CFR 1010.5 (c) 1-13

1. Attached is a letter from the Crane Division, US Navy requesting the use of ANSI Z136.1-1996 be the standard for this laser product.
2. See attached letter from the Crane Division, US Navy.
3. See attached letter from the Crane Division, US Navy.
4. This laser product is a range finder used by the Navy in an infrared camera for surveillance. The ANSI classification of this product is Class I.
5. FDA requires the radiant energy to be measured using a 17mm aperture on a 50 mm lens. This results in a typical radiant energy of 10 milliJoules @ for a 20ns pulse at 1536 nm. FDA standard for Class I laser product is 7.9 milliJoules maximum. The rationale for the FDA standard is that because the beam diameter is larger than the eye's pupil, only a small (safe level) of energy could enter the naked eye; however a pair of binoculars could collect all the energy and funnel it into the eye. This rationale negates the fact binoculars have poor optical transmission at the IR wavelength of the laser, and the energy reaching the eye would be at a safe level. Under the ANSI scenario, the energy should be measured using a 7 mm aperture. In addition, 21 CFR 1040.10(e)(3)(i) allows the use of a 7 mm aperture for measurement in a locale where the emitted laser radiation is unlikely to be viewed with optical instruments: as is the case with which these laser rangefinders are used by the Navy in a surveillance situation. It is extremely rare for the target to be aware that they are under surveillance by the infrared camera with the laser range finder.
6. The proposal is to accept the radiant energy using a 7 mm aperture instead of a 17 mm aperture. Measurement using a 7 mm aperture will result in 4milliJoules. See attached e-mail from the laser manufacturer.
7. This deviation will allow the US Navy or other government agencies to utilize this laser product for national security interest.
8. No additional protection would be required as this will be a Class I laser.
9. This exemption is to be applicable to all laser range finders procured by the Crane Division, US Navy and all subsequent government agencies that will procure this product for surveillance use.
10. The system manufacturer is FLIR Boston, Inc. 16 Esquire Road, North Billerica, MA 01862, telephone number 978-901-8000. The laser manufacturer is Advanced Laser Systems Technology, Inc. 6860 Edgewater Commerce Parkway, Suite 500, Orlando, FL32810.
11. Department of the Navy, Crane Division, naval Surface Warfare Center, 300 Highway 361, Crane, IN 47522-5000
12. N/A
13. N/A



DEPARTMENT OF THE NAVY

CRANE DIVISION
NAVAL SURFACE WARFARE CENTER
300 HIGHWAY 361
CRANE, INDIANA 47322-5000

IN REPLY REFER TO:

4222
31 August 1999
Ser 1165ZH/9231

*Copy to Mr. Dan
Please execute
Dan*

Mr. Dan Manidakos
Inframetrics Inc.
16 Esquire Road
North Billerica, MA 01863-2598

Subj: MARFLIR System Contracts N00164-98-D-0037 and N00164-98-D-0039

Ref: (a) MARFLIR System Safety Submission Initial Report Amendment, 16 Nov 1998
(b) MARFLIR Eyesafe Laser Rangefinder Laser Hazard Evaluation, June 1999

Request Inframetrics apply to the Federal Drug Administration (FDA) for a Variance from 21 CFR 1040.10(e)(3(i)) to permit the use of a 7 millimeter diameter measuring aperture vice the 50 mm diameter measuring aperture for the Lot I MARFLIR Systems on Contract Number N00164-98-D-0037 and N00164-98-D-0039. Inframetrics submitted reference (a) and has been assigned an FDA Accession Number 9811735.

The U.S. Navy tested the Lot I MARFLIR System at Inframetrics on 24 June 1999. The results of the testing determined the Lot I MARFLIR System is a Class 1 laser system as defined by ANSI Z136.1-1993 per the test results in reference (b).

The FDA utilizes a different standard, IEC 6085.1, for laser classification than the U.S. Navy and this is the reason the Government requests Inframetrics apply for the variance.

NAVSURFWARCEN Crane Contract Point of contact is Ms. Vonda Pollock, telephone (812) 854-3683.

Sincerely,

MARY E. SHEETZ
by direction of
the Commander

Author: alst1@iag.net (Dennis Bellar; ALST Inc.) at INFRANET
Date: 8/18/99 4:48 PM
Priority: Normal
TO: Kin Wong at INFRA
Subject: Laser Safety Measurements

----- Message Contents -----

Kin;

ALST has made this measurement for a laser with the same specifications and beam expander as the laser that you are evaluating.

For the laser tested, the average pulse energy was 9.5 millijoules, full beam. 3.8 millijoules was transmitted through a 7 millimeter aperture. This is 40%. If the average beam energy was 10 millijoules, then 4 millijoules would be transmitted through the 7 millimeter aperture.

The same beam was measured to transmit 0.15 millijoules through a 1.0 millimeter aperture, and 1.5 millijoules through a 3.5 millimeter aperture. All of these values are consistent with Class 1 under the ANSI Z-136.1-1993 Standard for the Safe Use of Lasers.

Best Regards,
Dennis Bellar

FedEx USA Airbill FedEx Tracking Number 8131 3499 8280

From This portion can be removed for Recipient's records.

Date 9/3/99 FedEx Tracking Number

813134998280

Sender's Name KIN WONG Phone 978 501-8000

Company FLIR SYSTEMS/ BOSTON

Address 15 ESQUIRE RD STE 1

City NORTH BILLERICA State MA ZIP 01862

Your Internal Billing Reference

To DOCKET MANAGEMENT
Recipient's Name BRANCH (HEA-305) Phone
FED & DRUG ADMINISTRATION

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12400 PARKLAWN DRIVE

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We cannot deliver to PO boxes or PO ZIP codes

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Form I.D. No.

0215

4a Express Package Service

☐ FedEx Priority Overnight
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Packages up to 150 lbs.
Delivery commitment may be later in some areas.
☐ FedEx First Overnight
Earliest next business morning delivery to select locations

☐ FedEx 2Day*
Second business day

☐ FedEx Express Saver*
Third business day

* FedEx Letter Rate not available
Minimum charge: One-pound rate

4b Express Freight Service

☐ FedEx 1Day Freight*
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☐ FedEx 2Day Freight
Second business day

Packages over 150 lbs.
Delivery commitment may be later in some areas.
☐ FedEx 3Day Freight
Third business day

* Call for Confirmation

5 Packaging

☒ FedEx Letter*

☐ FedEx Pak*

* Declared value limit \$500
☐ Other Pkg.
Includes FedEx Box, FedEx Tube, and customer pkg.

6 Special Handling

☐ Saturday Delivery
Available for FedEx Priority Overnight and FedEx 2Day to select ZIP codes

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Available for FedEx Priority Overnight to select ZIP codes

☐ HOLD Weekday at FedEx Location
Not available with FedEx First Overnight

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Does this shipment contain dangerous goods?

One box must be checked.

☒ No

☐ Yes

As per attached Shipper's Declaration

☐ Yes

Shipper's Declaration not required

☐ Dry Ice

Dry Ice, S. UN 1845

x kg

Dangerous Goods cannot be shipped in FedEx packaging

☐ Cargo Aircraft Only

7 Payment Bill to:

☒ Sender
Acct. No. in Section 7 will be billed

☐ Recipient

☐ Third Party

☐ Credit Card

☐ Obtain Recip. Acct. No.
☐ Cash/Check

Total Packages

Total Weight

Total Charges

Credit Card Auth.

8 Release Signature

Sign to authorize delivery without obtaining signature.

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.
Questions? Call 1-800-Go-FedEx (800-463-3339)
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